



HHS Bill Report; 1988; H.R.1207; **Prescription Drug Marketing Act**

APR 11 1988

The Honorable James C. Miller III  
Director, Office of Management  
and Budget  
Washington, D.C. 20503

Dear Mr. Miller:

This is in response to your request for a report on H.R. 1207, an enrolled bill entitled the "**Prescription Drug Marketing Act** of 1987".

We recommend that the President approve the enrolled bill. Given the overwhelming congressional support for the bill, we believe it would be pointless for the President to disapprove it, although we believe the bill inappropriately addresses an economic issue through a public health statute, and would divert enforcement resources from the task of protecting the public health.

H.R. 1207 would amend the Federal Food, **Drug**, and Cosmetic Act (FFD&C Act) to prohibit the reimportation of American-made pharmaceuticals except by the manufacturer or in an emergency; prohibit the trading, selling or purchasing of **drug** samples and coupons and the counterfeiting of such coupons; prohibit the resale of pharmaceuticals by hospitals and charitable organizations except under certain conditions; restrict the distribution of **drug** samples by sales representatives and permit an alternative distribution system by mail or common carrier; require Federal standards for the licensure of **drug** wholesalers; and establish civil and criminal penalties for violations of these provisions.

The rationale given for H.R. 1207 is to reduce potential public health risks that may result from **drug** counterfeiting, the **marketing** of reimported drugs, and the redistribution of drugs intended to be used as samples as well as drugs being bought and sold by certain non-profit institutions. The bill's sponsors have stated the intent to reduce the risk, such as it may be, that drugs will become ineffective or otherwise adulterated as a result of "gray market" diversion. It is our understanding that this legislation is also intended, and in any case its effect will be, to eliminate a source of competition in the domestic **drug** market through the diversion into the domestic market of **prescription** drugs which have been sold at prices below the domestic wholesale price either for export, to non-profit health facilities, or for promotional purposes.

Despite concerns expressed by the bill's sponsors, little actual risk to the public health has been shown to be linked with the business practices this legislation is designed to curb. To the extent that reimported or redistributed drugs might be subpotent, outdated, mislabeled, or counterfeited, the Department's Food and **Drug** Administration (FDA) has ample authority to deal with these problems under current law.

In the absence of any significant public health issue, we believe it is inappropriate to address an economic issue, in this case competition, through a public health statute like the FFD&C Act. We are also concerned that H.R. 1207 may impose on FDA (and on its counterpart State and local agencies) substantial costs not justified by the largely speculative risks connected with **drug**

diversion, and the withdrawal of resources from tasks more critical to the agency's mission of ensuring a safe and effective drug supply.

For the foregoing reasons the Department opposed enactment of the bill during its consideration by the Congress.

Nevertheless, we note that the bill has overwhelming bipartisan support in both House and Senate. The bill was introduced in the House by the Chairman of the Committee on Energy and Commerce, and had 40 additional cosponsors, including the chairman of the subcommittee within Energy and Commerce with legislative jurisdiction over the Department. The companion bill in the Senate had 27 cosponsors. The bill passed both Houses by voice votes, virtually without opposition. In these circumstances it is virtually certain that a veto of the bill would be overridden, and would only serve to strain our relations with the Congress and in particular with the House Committee.

We therefore recommend that the President approve the enrolled bill.

Sincerely,

/s/ Otis R. Bowen, M.D.  
Secretary